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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/628,494	07/28/00	MIGNOT E	STAN-147

EXAMINER	
SOUAYA, I	
ART UNIT	**PAPER NUMBER**
1655	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/628,494	Mignot et al
Examiner	**Art Unit**
Jehanne Souaya	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Aug 24, 2001 .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-45 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-45 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 5-12, and 38-45, drawn to a method for detecting a predisposition to a disorder in a subject caused by an alteration in hypocretin receptor activity using nucleic acid based assays, and to nucleic acids for detecting polymorphisms in hypocretin receptor, classified in class 435, subclass 6; and class 536, subclass 23.1 respectively.

II. Claims 4 and 32-37, drawn to detecting a predisposition to a disorder or to methods of detecting a sleep disorder or a predisposition to a sleep disorder using protein based assays, classified in class 435, subclass 7.1.

III. Claims 13-26, drawn to a method for screening biologically active agents that modulate sleep through modulation of hypocretin receptor activity, and to methods of treatment, classified in class 424, subclass 130.1.

IV. Claims 27-31, drawn to methods for detecting a predisposition to a sleep disorder by detecting an autoimmune response, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I, III, and IV are patentably distinct from each other because the methods require different products having different structures and functions. The nucleic acids of

group I are composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polypeptides for use in the methods of group II are composed of amino acids linked by peptide bonds and can assume complex tertiary structures. The methods comprising detecting an autoimmune response of group IV require antibodies which are composed of amino acids linked by peptide bonds which are glycosylated and comprise unique tertiary structures. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups I, II, and III are patentably distinct from each other.

The method of Groups III is patentably distinct from the methods of Groups I, II, and IV as the reagents, reaction parameters, and reaction conditions required for methods of treatment and for screening biologically active compounds are different from those required for the methods of detecting a predisposition to a sleep disorder of Groups I, II, and IV. Furthermore, the methods of treatment and for screening biologically active compounds are unobvious over the methods of detecting a predisposition to a sleep disorder of Groups I, II, and IV.

Please note, if group I is elected, applicants must further elect a nucleic acid that detects a single polymorphism (refers to claims 39-42, 45) as these nucleic acids are drawn to nucleic acids that encode different proteins. This is NOT an election of species. Furthermore, applicants are required to indicate which primers in claim 44 are directed to the polymorphism elected as a search of all 22 primers represents a serious to the burden to the examiner and the office and are subject to restriction requirement if they are drawn to different nucleic acids encoding different

proteins. The specification does not set forth the relationship between the nucleic acids of SEQ ID NOS 13, 15, and the nucleic acids encoding the amino acids of SEQ ID NOS 10, and 11, or the polymorphism of claim 45, thus absent evidence to the contrary, these sequences and polymorphisms appear to be directed to nucleotide sequences encoding different proteins. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a).

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-IV, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Patent examiner
September 19, 2001

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
9/20/01